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CHURCH & DWIGHT CO., INC. LAW DEPT. - PATENTS 469 NORTH HARRISON STREET PRINCETON, NJ 08543-5297			EXAMINER KASHNIKOW, ERIK	
			ART UNIT 1794	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/598,366	Applicant(s) BLUM ET AL.	
	Examiner ERIK KASHNIKOW	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 7-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2 and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 6-9 of U.S. Patent No. 7,086,403. Although the conflicting claims are not identical, they are not patentably distinct from each other because for claims 1-3 the only difference is that the instant claims say the lubricant is for heat, while the patents claims state that the lubricant is for desensitizing, however as they are comprised of the same materials their physical and chemical properties would intrinsically be the same. It is further pointed out that the disclosure of 44 and 68.2% polypropylene glycol falls within the range of at least 10% required in the instant claims. With regards to claims 4-5 it has been shown that absent

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a showing of criticality with respect to "concentration of polyethylene glycol" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the "concentration of polyethylene glycol" through routine experimentation to values, including those presently claimed in order to achieve "an effective lubricant". It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In regards to claim 9 it has been shown that absent a showing of criticality with respect to "amount of lubricant applied to inner and outer layer" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the "amount of lubricant on the inner and outer layer" through routine experimentation to values, including those presently claimed in order to achieve "an effective lubricant". It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). While the patent does not disclose the condom being packaged, it would have been obvious to one of ordinary skill in the art at the time of the invention to package the condom in order to preserve its effectiveness.

Claims 1-6 and 9 directed to an invention not patentably distinct from claim 1, 2 and 6-9 of commonly assigned 7,086,483. Specifically, see the reasons above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 7,086,483, discussed above, would form the basis

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for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. (US 2002/0103414).

4. In regards to claims 1 Harrison et al. teach a condom with lubrication, wherein the lubrication comprises 44% or 68.2% propylene glycol (claims 8 and 9). While there is no disclosure that the lubricant is a warmth inducing lubricant as presently claimed,

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given that Harrison et al. disclose lubrication composition identical to that claimed and comprising propylene glycol in amounts claimed, it is clear that the lubricating composition would inherently warm upon contact with compositions containing free water. Claim 12 teaches an embodiment wherein the condom is packaged.

5. In regards to claim 2 Harrison et al. teach a lubricant containing the glycol and glycerol polymethacrylate applied to the inner and outer surface of the sheath (paragraphs 0009 and 0010).

6. As discussed above Harrison et al. teach a condom with lubricant disposed on both sides, however they are silent regarding concentrations of polyethylene glycol above 30% and the amount of lubricant applied to the condom.

7. While Harrison et al. teach propylene glycol used with polyethylene glycol (claims 8 and 9) they are silent with regards to concentrations of propylene glycol being over 30%, however it has been shown that absent a showing of criticality with respect to "concentration of polyethylene glycol" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the "concentration of polyethylene glycol" through routine experimentation to values, including those presently claimed in order to achieve "an effective lubricant". It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA. 1980).

8. In regards to claim 8 Harrison et al. teaches the inclusion of glyceryl polymethacrylate polypropylene glycol and water (claims 8 and 9). While Harrison et al. are silent with regards to the specific composition in claim 8 it has been shown that

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absent a showing of criticality with respect to "concentrations of polyethylene and propylene glycol, glycerin and a mixture of glyceryl polymethacrylate, propylene glycol and water" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the " concentrations of polyethylene and propylene glycol, glycerin and a mixture of glyceryl polymethacrylate, propylene glycol and water " through routine experimentation to values, including those presently claimed in order to achieve "an effective condom lubricant". It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

9. In regards to claim 9 it has been shown that absent a showing of criticality with respect to "amount of lubricant applied to inner and outer layer" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the "amount of lubricant on the inner and outer layer" through routine experimentation to values, including those presently claimed in order to achieve "an effective lubricant". It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

10. Claims 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. (US 2002/0103414) in view of Ahmad et al. (US 2003/0211161).

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11. As stated above Harrison et al. teach condoms with lubricants that give a warming sensation, however they are silent with regard to glycerin.
12. Harrison et al. teach condoms with lubrication applied therein (Abs).
13. In regards to claim 7 Ahmad et al. teach the inclusion of glycerin in the lubricants (paragraph 0062).
14. One of ordinary skill in the art at the time of the invention would be motivated to modify the invention of Harrison et al. with that of Ahmad et al. because the invention of Ahmad et al. offers more warmth imparting sensation without irritation (paragraph 0001).

Response to Arguments

15. Applicant's arguments, see arguments, filed 09/28/09, with respect to the Lezdey et al. reference have been fully considered and are persuasive. The rejection of the claims has been withdrawn.
16. In regards to Applicant's arguments regarding the lubricants applied to the inner and outer layers, it is pointed out that the claim merely requires that the lubricating composition be applied to the inner and outer layer. It is noted that the claim uses open language (i.e. comprising) when describing the lubricating composition. It is therefore pointed out that the instant claims require a lubricating composition, which comprises the limitations set forth in the instant claims, but is using open language, and is therefore not limited to the requirements set forth in the claim. There is also no requirement that the composition be exactly the same, the only requirement is that the composition comprise the required ingredients presented in the instant claim.

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Paragraphs 0021-0024 of Harrison et al. state that the lubricating agent applied to the inner and outer surfaces differ only in that one does not have the desensitizing agent and has the same compounds, but with different viscosities. As such a fair reading of the reference shows that a lubricating composition, which complies with the instant limitations is applied to the inner and outer surface of the condom.

17. In regards to Applicants arguments that the Harrison reference consistently shows embodiments wherein the propylene glycol has a higher concentration than the polyethylene glycol Examiner points out that the courts have ruled that “applicant must look to the whole reference for what it teaches. Applicant cannot merely rely on the examples and argue that the reference did not teach others.” In re Courtright, 377 F.2d 647, 153 USPQ 735,739 (CCPA 1967).

18. In regards to Applicants arguments regarding the Harrison et al. reference being silent with regards to the lubricating agent warming upon contact with water, it is first noted that paragraph 4 of the previous office action set forth reasoning and facts as to the interpretation that the lubrication agent of Harrison et al. would also warm upon contact with water. Further it is noted that discovery of a new property from a composition already known in the art, in this instance the warming of the lubricant when it comes in contact with free water, cannot be the basis of patentability (MPEP 2145 II).

19. In regards to Applicant’s arguments regarding the packaging process it is noted that the packaging is obvious over the Harrison et al. reference, as Claim 12 teaches the packaging step and the rest of the rejection was based on an obvious to optimize rejection. Applicants arguments that the package is for a condom different than that

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instantly claimed is not persuasive for the reasons set forth above further it is pointed out that there is nothing in the instant article or packaging claims that requires the condom be free of a desensitizing agent, nor as to which surface a lubricant with a higher viscosity must be applied.

20. In regards to Applicants arguments regarding the criticality requirement in the previous rejection, it is noted that the arguments presented are not persuasive. One way Applicant's can meet the criticality requirement by showing that the required concentrations in the instant claim would produce unexpected results.

21. In regards to Applicant's arguments regarding the data presented in the instant specification, it is noted that in order to show unexpected results Applicant's must compare their results to that of the closest prior art. In this instance Applicants have presented the results obtained from the instant invention but have not shown how this would compare to the closest prior art, in this case, Modified Harrison et al.

22. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Harrison et al. and Ahmed et al. teach lubricated condoms, and Ahmed et al. offers the ability to

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produced increase warmth without irritation, which would motivate one of ordinary skill in the art at the time of the invention to combine Harrison et al. and Ahmed et al.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIK KASHNIKOW whose telephone number is (571)270-3475. The examiner can normally be reached on Monday-Friday 7:30-5:00PM EST (Second Friday off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Erik Kashnikow
Examiner
Art Unit 1794

/Rena L. Dye/
Supervisory Patent Examiner, Art Unit 1794